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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/764,429
Filing Date	January 23, 2004
First Named Inventor	ZDEBLICK, MARK
Group Art Unit	3766
Examiner Name	LEE, YUN HAENG NMN
Attorney Docket Number	PRTS-038US2

Total Number of Pages in This Submission: 29

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Documents
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☒ **Petition for Certificate of Correction w/supporting documents (28 pages)**
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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Certificate
JUL 11 2007
of Correction

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	**BRET E. FIELD, 37,620** **BOZICEVIC, FIELD & FRANCIS, LLP**
Signature	
Date	**July 5, 2007**

EXPRESS MAIL LABEL NO. EV 954 013 625 US

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PETITION FOR CERTIFICATE OF CORRECTION		
	Attorney Docket	PRTS-038US2
	First Named Inventor	ZDEBLICK, MARK
	Patent Number	7,200,439
	Issue Date	April 3, 2007
	Application Number	10/764,429
	Filing Date	January 23, 2004
Address to: Mail Stop Certificate of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Title: *"METHOD AND APPARATUS FOR ENHANCING CARDIAC PACING"*	

Sir:

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent.

- In claim 14: Please delete the word 'cave' and replace with 'cava'.
- In claim 54: Please delete the word 'heat' and replace with 'heart'.
- In claim 68: Please delete the word 'head' and replace with 'heart'.
- In claim 92 delete the word 'Feast and replace with 'least'.
- In column 3 line 43 please delete the word 'head' and replace with 'heart'.
- In column 25 line 5 please delete the word 'Anziography' and replace with 'Angiography'
- In column 40 line 37 please delete the word 'dysfumctional' and replace with 'dysfunctional'.

Enclosed is a copy of the last amendment as filed August 31, 2006 reflecting the above requested claim language. Also enclosed is a copy of the pages 4, 32 & 53 of the specification as filed reflecting the above requested specification language.

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815 order number PRTS-038US2.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

July 5, 2007

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO : 7,200,439
DATED : April 3, 2007
INVENTOR(S) : ZDEBLICK, MARK, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- In claim 14: Please delete the word 'cave' and replace with 'cava'.
- In claim 54: Please delete the word 'heat' and replace with 'heart'.
- In claim 68: Please delete the word 'head' and replace with 'heart'.
- In claim 92 delete the word 'Feast and replace with 'least'.
- In column 3 line 43 please delete the word 'head' and replace with 'heart'.
- In column 25 line 5 please delete the word 'Anziography' and replace with 'Angiography'
- In column 40 line 37 please delete the word 'dysfumctional' and replace with 'dysfunctional'.

MAILING ADDRESS OF SENDER:

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PATENT NO. 7,200,439

No. of additional copies

JUL 11 2007

Thus, generally, "characteristic" and "parameter" may be used interchangeably to mean "value," "amount" or the like.

[0010] In some embodiments the characteristic of the heart is measured again, after the adjusting step, the cardiac performance parameter is calculated again, and the pacing device is adjusted again. This series of steps may be repeated any number of times, and is sometimes repeated many times, to provide multiple data points to help a physician select/adjust settings for a pacing device. In some embodiments, for example, multiple data points may be displayed to the physician on a display monitor or other display device for multiple timing settings of a pacing device. Data may be displayed as a graph, for example, such as a three-dimensional graph.

[0011] In some embodiments, measuring the at least one characteristic comprises measuring with at least one sensor device implanted in at least one wall of the heart. Alternatively, measuring the at least one characteristic may comprise measuring with at least one catheter device disposed in at least one chamber of the heart. In other embodiments, both at least one catheter and at least one implanted sensor device may be used. For example, in some embodiments a multiplexed catheter is used, and the catheter may be placed at least partially within at least one of a left ventricle and a right ventricle of the heart.

[0012] In some embodiments, measuring the at least one characteristic comprises measuring at least one of pressure, volume, blood flow velocity, blood oxygen concentration, carbon dioxide concentration, wall stress, wall thickness, force, electric charge, electric current and electric conductivity. Such characteristics may be measured in any part of the heart, such as one or more chambers and/or one or more walls of the heart, or in blood vessels in and around the heart or adjacent to the heart.

[0013] In some embodiments, calculating the at least one cardiac performance parameter comprises calculating at least one of ejection fraction, cardiac output, cardiac index, stroke volume, stroke volume index, pressure reserve, volume reserve, cardiac reserve, cardiac reserve index, stroke reserve index, myocardial work, myocardial work index, myocardial reserve, myocardial reserve index, dP/dt, d^2P/dt, stroke work, stroke work index, stroke work reserve, stroke work reserve index, systolic ejection period, stroke power, stroke power reserve, stroke power reserve index, myocardial power, myocardial power index, myocardial power reserve, myocardial power reserve index, myocardial power requirement, ejection

above. In one embodiment, one or more ultrasound transducers are used to measure the ventricular volume continuously while the balloon is inflated during systole and deflated in diastole to reduce the end-diastolic pressures and/or volumes.

[0088] Methods for Determining End-Systolic Volume

[0089] One method for measuring LVESV is to record LVV when it is at a minimum, using one of the continuous volume measuring systems. An alternative method for measuring for LVESV is that LVV when aortic flow rate is first zero following its maximum. The difference in volumes of these two recordings is equal to the combination of mitral regurgitant flow and left-to-right shunt flow after the aortic valve is closed.

[0090] Methods for Determining Ejection Fraction

[0091] Ejection Fraction is typically defined as the ratio of the difference between end-diastolic volume and end-systolic volume over end-diastolic volume. This calculation may be made, using any of the above-described methods of measuring EDV and ESV.

[0092] Methods for Determining Cardiac Output, Cardiac Index, Stroke Volume, and Stroke Volume Index on a Per-Stroke Basis

[0093] In one embodiment, a blood velocity or flow rate sensor is coupled with the catheter and inserted into the aorta. This sensor samples the velocity of blood at regular intervals, such as approximately once every millisecond, and transmits that information to a controller or other processor. The controller then determines the average blood velocity by averaging the readings taken over a second (or some other similar period of time that is representative of the next step). During that sampling time, the cardiac output is independently measured using one of the accepted methods, such as Fick's Law using oxygen consumption or a dilution method (thermal dilution, conductance dilution or dilution with a dye). (Grossman's Cardiac Catheterization and Angiography, pp. 101-117 describes these methods in detail). The cardiac output thus measured is divided by the average velocity or flow rate to determine a scaling coefficient. This coefficient assumes that the aortic cross section near the velocity or flow rate sensor is reasonably constant during the sampled cycle and successive cycles. A number of different methods of measuring blood velocity or flow rate are possible, including thermal dilution, shear force measurement, a pitot-tube method (stagnant versus dynamic flow), Ultrasound Doppler, and/or any other suitable method. Once the scaling factor has been determined, the stroke volume may be determined for any given cycle and is equal to

cava, and thus, if used to set heart rate, would lead to a lower than desirable heart rate. If a shunt exists, develops or is expected in a patient, the device may be implanted with an electronic cardiac output sensor multiplexed into the pacing lead or perhaps attached to a separate lead that floats in the pulmonary artery. Alternatively or additionally, a blood oxygen sensor may be placed on the lead in the superior vena cava as well as in the right ventricle. A divergence of signals from the vena cava and the left ventricle would indicate the presence of a shunt. Thus, the pacing device could use the blood oxygen levels in the superior and / or inferior vena cava instead of the blood oxygen level in the left ventricle to help determine heart rate. In addition, the cardiac output sensor may be used in conjunction with the left and right pressures available to a trans-septal implant to determine systemic vascular resistance. It is likely that measurements such as systemic vascular resistance do not need to be made every heart beat, but rather sampled at a less frequent pace unless they seem to be changing rapidly.

[0161] A diseased heart often fails faster on the left side than on the right. This asynchronous function may lead to a dysfunctional response to temporary volume overload, which may quickly cause the heart spiral into severe heart failure. Thus, some embodiments of the invention involve measuring both left and right ventricular pressures to set the delay between the Right Atrial and Right Ventricular contractions. By varying this delay, one may control the output of the right ventricle and thus control the left ventricular end diastolic pressure to a desired level.

[0162] Thus, in one embodiment a method of Atrial-Ventricular (A-V) pacing varies the efficiency of the right ventricle to actively control the end diastolic pressure of the left ventricle within a desired range. This "LVEDP Control Range" may be a function of other sensors, such as activity or blood oxygen or systemic vascular resistance sensors, so that higher operating pressures are available when there is a biological need for it, but lower when the patient is not exercising. The efficiency and thus the stroke volume of the right ventricle is varied by adjusting the timing delay between when the Atrium contracts and when the Ventricle contracts. Thus, if a sensor measures the LVEDP to be above the LVEDP Control Range, the pacing system will shorten the time delay between when the Right Atrium contracts and when the Right Ventricle contracts. In some cases, the doctor may allow the pacing system to let the ventricle contract before the atrium, further reducing its efficiency and stroke volume.

VIA ELECTRONIC FILING

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. §1.111		
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	PRTS-038US2
	Confirmation No.	6078
	First Named Inventor	ZDEBLICK, MARK
	Application Number	10/764,429
	Filing Date	January 23, 2004
	Group Art Unit	3766
	Examiner Name	LEE, YUN HAENG NMN
	Title: "METHOD AND APPARATUS FOR ENHANCING CARDIAC PACING"	

Sir:

This communication is responsive to the Office Action dated July 20, 2006 for which a three-month period for response was given making this response due on or before October 20, 2006.

JUL 11 2007

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [012] beginning on page 4 with the following rewritten paragraph:

In some embodiments, measuring the at least one characteristic comprises measuring at least one of pressure, volume, blood flow velocity, blood oxygen concentration, carbon dioxide concentration, wall stress, wall thickness, force, electric charge, electric current and electric conductivity. **For instance, in certain embodiments, the measuring of at least one characteristic comprises measuring at least one blood oxygen concentration in a patient having a shunt.** Such characteristics may be measured in any part of the heart, such as one or more chambers and/or one or more walls of the heart, or in blood vessels in and around the heart or adjacent to the heart.

AMENDMENTS TO THE CLAIMS

In the Claims:

1. (Currently Amended) A method of enhancing cardiac pacing, the method comprising:

measuring at least one characteristic of a heart using one or more parameter measuring devices disposed in the heart;

calculating at least one cardiac performance parameter using the at least one measured characteristic; ~~and~~

accepting at least one command from a user, said command assigning a relative weight to said at least one cardiac performance parameter, and

automatically adjusting at least one functional parameter of a cardiac pacing device**, wherein said adjusting comprises determining said adjustment to be made to the at least one functional parameter based on the at least one cardiac performance parameter and said assigned relative weight of said at least one cardiac performance parameter**.

2. (Original) A method as in claim 1, wherein the at least one functional parameter is automatically adjusted based on the at least one calculated cardiac performance parameter.

3. (Original) A method as in claim 1, wherein measuring the at least one characteristic comprises measuring with at least one sensor device implanted in at least one wall of the heart.

4. (Original) A method as in claim 1, wherein measuring the at least one characteristic comprises measuring with at least one catheter device disposed in at least one chamber of the heart.

5. (Original) A method as in claim 4, wherein measuring the at least one characteristic further comprises measuring with at least one sensor device implanted in at least one wall of the heart.

6. (Original) A method as in claim 4, wherein the at least one catheter comprises a catheter positioned only in the right side of the heart.

7. (Original) A method as in claim 4, wherein the at least one catheter comprises a multiplexed catheter.

8. (Original) A method as in claim 7, wherein the at least one multiplexed catheter is disposed at least partially within at least one of a left ventricle and a right ventricle of the heart.

9. (Original) A method as in claim 1, wherein measuring the at least one characteristic comprises measuring at least one of pressure, volume, blood flow velocity, blood oxygen concentration, carbon dioxide concentration, wall stress, wall thickness, force, electric charge, electric current and electric conductivity.

10. (Original) A method as in claim 9, wherein each characteristic is measured in at least one of a chamber of the heart, a wall of the heart and a blood vessel adjacent the heart.

11. (Original) A method as in claim 9, wherein measuring comprises:

measuring at least one blood oxygen concentration in at least one chamber on the left side of the heart; and

measuring at least one blood oxygen concentration in at least one chamber on the right side of the heart.

12. (Original) A method as in claim 11, further comprising:

measuring a systemic vascular resistance; and

automatically adjusting the cardiac pacing device based on at least one of the measured blood oxygen concentrations and on the measured systemic vascular resistance.

13. (Original) A method as in claim 1, wherein measuring the at least one characteristic comprises measuring at least one blood oxygen concentration in a patient having a shunt.

14. (Original) A method as in claim 13, further comprising positioning at least a portion of a parameter measuring device in at least one of a pulmonary artery, a superior vena cava, an inferior vena cava and a right ventricle, wherein the portion of the parameter measuring device includes means for measuring blood oxygen content.

15. (Original) A method as in claim 14, wherein automatically adjusting comprises adjusting the cardiac pacing device based on at least one blood oxygen content measured by the parameter measuring device.

16. (Original) A method as in claim 1, wherein calculating the at least one cardiac performance parameter comprises calculating at least one of ejection fraction, cardiac output, cardiac index, stroke volume, stroke volume index, pressure reserve, volume reserve, cardiac reserve, cardiac reserve index, stroke reserve index, myocardial work, myocardial work index, myocardial reserve, myocardial reserve index, stroke work, stroke work index, stroke work reserve, stroke work reserve index, systolic ejection period, stroke power, stroke power reserve, stroke power reserve index, myocardial power, myocardial power index, myocardial power reserve, myocardial power reserve index, myocardial power requirement, dP/dt, d^2P/dt, ejection contractility, cardiac efficiency, cardiac amplification, valvular gradient, valvular gradient reserve, valvular area, valvular area reserve, valvular regurgitation, valvular regurgitation reserve, a pattern of electrical emission by the heart, concentration of oxygen in the cardiac vein, and a ratio of carbon dioxide to oxygen.

17. (Original) A method as in claim 1, wherein the cardiac pacing device comprises one or more pacing leads.

18. (Original) A method as in claim 17, wherein at least one of the pacing leads comprises two or more electrodes disposed along its length.

19. (Original) A method as in claim 18, wherein the two or more electrodes are multiplexed with the at least one pacing lead.

20. (Original) A method as in claim 1, wherein adjusting the at least one functional parameter comprises adjusting at least one of a selected electrode of the cardiac pacing device to be activated, a pulse width of an activation of the cardiac pacing device, a pulse amplitude, a pulse duration, a number of pulses per one cycle of the heart, a pulse polarity, a pulse duty cycle, a timing of pulses relative to a cycle of the heart and a timing of pulses from multiple electrodes of the pacing device relative to one another.

21. (Currently Amended) A method as in claim 1, wherein ~~adjusting the at least one functional parameter~~ **said method further** comprises:

assigning a first relative weight to a first calculated cardiac performance parameter;

assigning a second relative weight to a second calculated cardiac performance parameter; and

determining **said** at least one adjustment to be made to the at least one functional parameter, based on the first and second calculated cardiac performance parameters and the first and second relative weights.

22. (Original) A method as in claim 21, further comprising:

assigning a third relative weight to a third calculated cardiac performance parameter; and

determining the at least one adjustment, based on the first, second and third calculated cardiac performance parameters and the first, second and third relative weights.

23. (Currently Amended) A method as in claim 21, further comprising:

determining at least one apparatus performance parameter of the cardiac pacing ~~apparatus~~ **device**;

assigning a third relative weight to the apparatus performance parameter; and

determining the at least one adjustment, based on the first and second calculated cardiac performance parameters, the at least one apparatus performance parameter and the first, second and third relative weights.

24. (Currently Amended) A method as in claim 23, wherein determining the at least one apparatus performance parameter comprises determining at least one of an energy consumption rate, a maximum current and a maximum voltage of the cardiac pacing ~~apparatus~~ **device**.

25. (Cancelled)

26. (Currently Amended) A method as in claim **1** ~~25~~, further comprising accepting an additional command from the user, the additional command assigning a relative weight to at least one apparatus performance parameter, wherein adjusting the at least one functional parameter comprises determining the adjustment based on the at least one cardiac performance parameter, the at least one apparatus performance parameter and the assigned relative weights of each.

27. (Original) A method as in claim 1, further comprising providing at least one calculated cardiac performance parameter to a user in the form of data.

28. (Original) A method as in claim 27, wherein the data is provided as one or more images on a display monitor.

29. (Original) A method as in claim 27, further comprising accepting at least one command from the user, the command designating one or more of the calculated cardiac performance parameters to be provided to the user.

30. (Original) A method as in claim 27, further comprising:

measuring the at least one characteristic of the heart after the adjustment step;

calculating the at least one cardiac performance parameter using the at least one re-measured characteristic; and

automatically adjusting at least one functional parameter of a cardiac pacing device.

31. (Original) A method as in claim 30, wherein the measuring, calculating and adjusting steps are performed multiple times, and wherein the calculated cardiac performance parameter is provided to the user in the form of data for each adjustment of the functional parameter of the pacing device.

32. (Original) A method as in claim 31, wherein the data is provided to the user in the form of a three-dimensional graph on a display monitor.

33. (Original) A method as in claim 1, wherein automatically adjusting comprises setting the cardiac pacing device to fire with a timing such that it does not fire during each heart cycle.

34. (Original) A method as in claim 33, wherein the timing is selected from the group consisting of firing once every two cycles, once every three cycles and once every four cycles.

35. (Original) A method as in claim 33, wherein setting the cardiac pacing device further comprises selecting at least one firing pattern from a group of possible firing patterns.

36. (Original) A method as in claim 1, wherein automatically adjusting comprises causing the cardiac pacing device to stimulate at least a first chamber of the heart before stimulating at least a second chamber of the heart.

37. (Original) A method as in claim 36, wherein the cardiac pacing device stimulates the right atrium before stimulating the right ventricle.

38. (Original) A method as in claim 36, wherein the cardiac pacing device stimulates both atria before stimulating both ventricles.

39. (Original) A method as in claim 36, wherein the cardiac pacing device stimulates the right ventricle before stimulating the left ventricle.

40. (Original) A method as in claim 36, wherein the cardiac pacing device stimulates the right ventricle before stimulating the right atrium.

41. (Original) A method as in claim 36, wherein the cardiac pacing device stimulates the left ventricle before stimulating the right ventricle or the right atrium.

42. (Original) A method as in claim 36, wherein automatically adjusting further comprises:

comparing at least one left ventricular end diastolic pressure measured by the parameter measuring device with a pre-defined left ventricular end diastolic pressure control range; and

adjusting the cardiac pacing device based on the comparison.

43. (Original) A method as in claim 42, further comprising:

measuring at least one right ventricular pressure; and

adjusting the cardiac pacing device based on the comparison and on the measured right ventricular pressure.

44. (Original) A method as in claim 1, wherein automatically adjusting comprises causing the cardiac pacing device to stimulate at least a first valve of the heart before stimulating at least a second valve of the heart.

45. (Original) A method as in claim 1, wherein measuring comprises:

measuring at least a first pressure using a first lead positioned in at least one of the right atrium and the right ventricle of the heart; and

measuring at least a second pressure using a second lead positioned in the coronary vein over the left ventricle of the heart.

46. (Original) A method as in claim 45, further comprising measuring an ambient pressure.

47. (Original) A method as in claim 45, wherein calculating comprises estimating a left ventricular pressure from the second pressure.

48. (Original) A method as in claim 45, wherein adjusting comprises adjusting timing of firing of the first and second leads.

49. (Original) A method as in claim 48, wherein adjusting the firing timing comprises adjusting the timing to minimize left ventricular end diastolic pressure.

50. (Original) A method as in claim 48, wherein adjusting the firing timing comprises adjusting the timing to minimize left ventricular end diastolic pressure in response to at least one measured parameter measured by at least one sensor.

51. (Original) A method as in claim 48, wherein adjusting the firing timing comprises adjusting the timing to increase left ventricular end diastolic pressure to increase cardiac output.

52. (Original) A method as in claim 48, wherein adjusting the firing timing comprises adjusting the timing to increase cardiac output in response to at least one measured parameter measured by at least one sensor.

53. (Currently Amended) A method of enhancing cardiac pacing **as in claim 1**, the method comprising:

measuring at least a first pressure using a first sensor positioned in at least one of the right atrium and the right ventricle of a heart;

measuring at least a second pressure using a second sensor positioned in the coronary vein over the left ventricle of the heart;

measuring an ambient pressure for use in calculating a gauge pressure; and

adjusting the cardiac pacing based on the measured first and second gauge pressures.

54. (Currently Amended) A method of enhancing cardiac pacing **as in claim 1**, the method comprising:

measuring at least one left ventricular end diastolic pressure;

measuring a proxy for ambient pressure for use in calculating a gauge pressure; and

adjusting the cardiac pacing based on the gauge pressure.

55. – 100 (Cancelled)

101. (New) A method of enhancing cardiac pacing, the method comprising:

measuring at least one characteristic of a heart using one or more parameter measuring devices disposed in the heart;

calculating at least one cardiac performance parameter using the at least one measured characteristic; and

automatically adjusting at least one functional parameter of a cardiac pacing device, wherein said adjusting comprises:

assigning a first relative weight to a first calculated cardiac performance parameter;

assigning a second relative weight to a second calculated cardiac performance parameter;

determining at least one apparatus performance parameter of the cardiac pacing device;

assigning a third relative weight to said apparatus performance parameter; and

determining at least one adjustment to be made to the at least one functional parameter, based on the first and second calculated cardiac performance parameters,

the at least one apparatus performance parameter and the first, second and third relative weights.

102. (New) A method as in claim 101, wherein measuring the at least one characteristic comprises measuring with at least one sensor device implanted in at least one wall of the heart.

103. (New) A method as in claim 101, wherein measuring the at least one characteristic comprises measuring with at least one catheter device disposed in at least one chamber of the heart.

104. (New) A method as in claim 103, wherein measuring the at least one characteristic further comprises measuring with at least one sensor device implanted in at least one wall of the heart.

105. (New) A method as in claim 103, wherein the at least one catheter comprises a catheter positioned only in the right side of the heart.

106. (New) A method as in claim 103, wherein the at least one catheter comprises a multiplexed catheter.

107. (New) A method as in claim 106, wherein the at least one multiplexed catheter is disposed at least partially within at least one of a left ventricle and a right ventricle of the heart.

108. (New) A method as in claim 101, wherein measuring the at least one characteristic comprises measuring at least one of pressure, volume, blood flow velocity, blood oxygen concentration, carbon dioxide concentration, wall stress, wall thickness, force, electric charge, electric current and electric conductivity.

109. (New) A method as in claim 108, wherein each characteristic is measured in at least one of a chamber of the heart, a wall of the heart and a blood vessel adjacent the heart.

110. (New) A method as in claim 108, wherein measuring comprises:

measuring at least one blood oxygen concentration in at least one chamber on the left side of the heart; and

measuring at least one blood oxygen concentration in at least one chamber on the right side of the heart.

111. (New) A method as in claim 110, further comprising:

measuring a systemic vascular resistance; and

automatically adjusting the cardiac pacing device based on at least one of the measured blood oxygen concentrations and on the measured systemic vascular resistance.

112. (New) A method as in claim 101, wherein measuring the at least one characteristic comprises measuring at least one blood oxygen concentration in a patient having a shunt.

113. (New) A method as in claim 112, further comprising positioning at least a portion of a parameter measuring device in at least one of a pulmonary artery, a superior vena cava, an inferior vena cava and a right ventricle, wherein the portion of the parameter measuring device includes means for measuring blood oxygen content.

114. (New) A method as in claim113, wherein automatically adjusting comprises adjusting the cardiac pacing device based on at least one blood oxygen content measured by the parameter measuring device.

115. (New) A method as in claim 101, wherein calculating the at least one cardiac performance parameter comprises calculating at least one of ejection fraction, cardiac output, cardiac index, stroke volume, stroke volume index, pressure reserve, volume reserve, cardiac reserve, cardiac reserve index, stroke reserve index, myocardial work, myocardial work index, myocardial reserve, myocardial reserve index, stroke work, stroke work index, stroke work reserve, stroke work reserve index, systolic ejection period, stroke power, stroke power reserve, stroke power reserve index,

myocardial power, myocardial power index, myocardial power reserve, myocardial power reserve index, myocardial power requirement, dP/dt, d^2P/dt, ejection contractility, cardiac efficiency, cardiac amplification, valvular gradient, valvular gradient reserve, valvular area, valvular area reserve, valvular regurgitation, valvular regurgitation reserve, a pattern of electrical emission by the heart, concentration of oxygen in the cardiac vein, and a ratio of carbon dioxide to oxygen.

116. (New) A method as in claim 101, wherein the cardiac pacing device comprises one or more pacing leads.

117. (New) A method as in claim 116, wherein at least one of the pacing leads comprises two or more electrodes disposed along its length.

118. (New) A method as in claim 117, wherein the two or more electrodes are multiplexed with the at least one pacing lead.

119. (New) A method as in claim 101, wherein adjusting the at least one functional parameter comprises adjusting at least one of a selected electrode of the cardiac pacing device to be activated, a pulse width of an activation of the cardiac pacing device, a pulse amplitude, a pulse duration, a number of pulses per one cycle of the heart, a pulse polarity, a pulse duty cycle, a timing of pulses relative to a cycle of the heart and a timing of pulses from multiple electrodes of the pacing device relative to one another.

120. (New) A method as in claim 101, wherein said determining the at least one apparatus performance parameter comprises determining at least one of an energy consumption rate, a maximum current and a maximum voltage of the cardiac pacing apparatus.

121. (New) A method as in claim 101, further comprising:

assigning a fourth relative weight to a third calculated cardiac performance parameter; and

determining the at least one adjustment, based on the first, second and third calculated cardiac performance parameters, the apparatus performance parameter, and the first, second, third and fourth relative weights.

122. (New) A method as in claim 101, further comprising providing at least one calculated cardiac performance parameter to a user in the form of data.

123. (New) A method as in claim 122, wherein the data is provided as one or more images on a display monitor.

124. (New) A method as in claim 122, further comprising accepting at least one command from the user, the command designating one or more of the calculated cardiac performance parameters to be provided to the user.

125. (New) A method as in claim 122, further comprising:

measuring the at least one characteristic of the heart after the adjustment step;

calculating the at least one cardiac performance parameter using the at least one re-measured characteristic; and

automatically adjusting at least one functional parameter of a cardiac pacing device.

126. (New) A method as in claim 125, wherein the measuring, calculating and adjusting steps are performed multiple times, and wherein the calculated cardiac performance parameter is provided to the user in the form of data for each adjustment of the functional parameter of the pacing device.

127. (New) A method as in claim 126, wherein the data is provided to the user in the form of a three-dimensional graph on a display monitor.

128. (New) A method as in claim 101, wherein automatically adjusting comprises setting the cardiac pacing device to fire with a timing such that it does not fire during each heart cycle.

129. (New) A method as in claim 128, wherein the timing is selected from the group consisting of firing once every two cycles, once every three cycles and once every four cycles.

130. (New) A method as in claim 128, wherein setting the cardiac pacing device further comprises selecting at least one firing pattern from a group of possible firing patterns.

131. (New) A method as in claim 101, wherein automatically adjusting comprises causing the cardiac pacing device to stimulate at least a first chamber of the heart before stimulating at least a second chamber of the heart.

132. (New) A method as in claim 131, wherein the cardiac pacing device stimulates the right atrium before stimulating the right ventricle.

133. (New) A method as in claim 131, wherein the cardiac pacing device stimulates both atria before stimulating both ventricles.

134. (New) A method as in claim 131, wherein the cardiac pacing device stimulates the right ventricle before stimulating the left ventricle.

135. (New) A method as in claim 131, wherein the cardiac pacing device stimulates the right ventricle before stimulating the right atrium.

136. (New) A method as in claim 131, wherein the cardiac pacing device stimulates the left ventricle before stimulating the right ventricle or the right atrium.

137. (New) A method as in claim 131, wherein automatically adjusting further comprises:

comparing at least one left ventricular end diastolic pressure measured by the parameter measuring device with a pre-defined left ventricular end diastolic pressure control range; and

adjusting the cardiac pacing device based on the comparison.

138. (New) A method as in claim 137, further comprising:

measuring at least one right ventricular pressure; and

adjusting the cardiac pacing device based on the comparison and on the measured right ventricular pressure.

139. (New) A method as in claim 101, wherein automatically adjusting comprises causing the cardiac pacing device to stimulate at least a first valve of the heart before stimulating at least a second valve of the heart.

140. (New) A method as in claim 101, wherein measuring comprises:

measuring at least a first pressure using a first lead positioned in at least one of the right atrium and the right ventricle of the heart; and

measuring at least a second pressure using a second lead positioned in the coronary vein over the left ventricle of the heart.

141. (New) A method as in claim 140, further comprising measuring an ambient pressure.

142. (New) A method as in claim 140, wherein calculating comprises estimating a left ventricular pressure from the second pressure.

143. (New) A method as in claim 140, wherein adjusting comprises adjusting timing of firing of the first and second leads.

144. (New) A method as in claim 143, wherein adjusting the firing timing comprises adjusting the timing to minimize left ventricular end diastolic pressure.

145. (New) A method as in claim 143, wherein adjusting the firing timing comprises adjusting the timing to minimize left ventricular end diastolic pressure in response to at least one measured parameter measured by at least one sensor.

146. (New) A method as in claim 143, wherein adjusting the firing timing comprises adjusting the timing to increase left ventricular end diastolic pressure to increase cardiac output.

REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1-24, 26-54 and 101-146, the only claims pending and under examination in this application after entry of the above amendments.

The specification has been amended to include the subject matter of original Claim 13.

Claims 1, 21, 23, 24, 26 and 53-54 have been amended. Claim 1 has been amended to incorporate the elements of Claim 25. Consequently, Claim 25 has been cancelled. Claims 21, 23 and 24 have been amended to clarify the claim language. Claims 26, 53 and 54 have been amended to correct their dependency. Claims 55 to 100 have been cancelled. New Claims 101-146 have been added. In total, 46 claims have been cancelled and 46 claims have been added.

New Claim 101 is a combination of original Claim 1, 21 and 23. New Claim 102 is derived from original Claim 3. New Claim 103 is derived from original Claim 4. New Claim 104 is derived from original Claim 5. New Claim 105 is derived from original Claim 6. New Claim 106 is derived from original Claim 7. New Claim 107 is derived from original Claim 8. New Claim 108 is derived from original Claim 9. New Claim 109 is derived from original Claim 10. New Claim 110 is derived from original Claim 11. New Claim 111 is derived from original Claim 12. New Claim 112 is derived from original Claim 13. New Claim 113 is derived from original Claim 14. New Claim 114 is derived from original Claim 15. New Claim 115 is derived from original Claim 16. New Claim 116 is derived from original Claim 17. New Claim 117 is derived from original Claim 18. New Claim 118 is derived from original Claim 19. New Claim 119 is derived from original Claim 20. New Claim 120 is derived from original Claim 24. New Claim 121 is derived from original Claim 22. New Claim 122 is derived from original Claim 27. New Claim 123 is derived from original Claim 28. New Claim 124 is derived from

original Claim 29. New Claim 125 is derived from original Claim 30. New Claim 126 is derived from original Claim 31. New Claim 127 is derived from original Claim 32. New Claim 128 is derived from original Claim 33. New Claim 129 is derived from original Claim 34. New Claim 130 is derived from original Claim 35. New Claim 131 is derived from original Claim 36. New Claim 132 is derived from original Claim 37. New Claim 133 is derived from original Claim 38. New Claim 134 is derived from original Claim 39. New Claim 135 is derived from original Claim 40. New Claim 136 is derived from original Claim 41. New Claim 137 is derived from original Claim 42. New Claim 138 is derived from original Claim 43. New Claim 139 is derived from original Claim 44. New Claim 140 is derived from original Claim 45. New Claim 141 is derived from original Claim 46. New Claim 142 is derived from original Claim 47. New Claim 143 is derived from original Claim 48. New Claim 144 is derived from original Claim 49. New Claim 145 is derived from original Claim 50. New Claim 146 is derived from original Claim 51.

Accordingly, no new matter has been added. As no new matter has been added by way of these amendments, entry thereof by the Examiner is respectfully requested.

As an initial matter, the Examiner is thanked for acknowledging the patentability of Claims 23-26.

Interview Summary

Applicants additionally thank the Examiner for the interview that was held on August 1, 2006, during which Claims 7, 13, 23 and 25 were discussed. Pursuant to the interview, the Applicants have amended the disclosure of the application to include the subject matter of Claim 13, have amended Claim 1 to recite the elements of Claim 25 and have added new claims 101-146 directed to the subject matter of Claim 23 in independent format, as discussed.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 13-15 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Applicants have amended the specification to include the subject matter of original Claim 13 which recites measuring a blood oxygen concentration in a patient having a shunt. Accordingly, in view of the amendment to the specification this rejection may be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1-11, 16-20, 27-45 and 47-52 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mulligan et al. (USPN 6,438,408) in view of Bennett et al. (USPN 5,213,098).

Claim 1 has been amended to incorporate the elements of Claim 25, which the Examiner has found to be allowable. Accordingly, Claim 1 as amended, as well as Claims 2-11, 16-20, 27-45 and 47-52 which ultimately depend from Claim 1, are all patentably distinct over the cited art and therefore the Applicants respectfully request that this rejection be withdrawn.

Claim 12 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mulligan et al. in view of Bennett et al., and further in view of Orth (USPN 5,423,323). Claim 12 ultimately depends from Claim 1. As set forth above, Claim 1 has been amended to include the elements of Claim 25, which the Examiner has found to be allowable. Accordingly, in view of the amendments to Claim 1, this rejection may be withdrawn.

Claims 21 and 22 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mulligan et al. in view of Bennett et al., and further in view of Nappholz et al. (USPN 5,188,106). Claims 21 and 22 ultimately depend from Claim 1. As set forth above, Claim 1 has been amended to include the elements of Claim 25, which the Examiner has found to be allowable. Accordingly, in view of the amendments to Claim 1, this rejection may be withdrawn.

Claims 46, 53 and 54 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mulligan et al. in view of Bennett et all, and further in view of Meador et al., (USPN 6,234,973). With respect to Claim 46, Claim 46 ultimately depends from Claim 1. With respect to Claims 53 and 54, these claims have been amended to depend from Claim 1. As set forth above, Claim 1 has been amended to include the elements of Claim 25, which the Examiner has found to be allowable. Accordingly, in view of the amendments to Claim 1, this rejection may be withdrawn.

New Claims

New Claims 101-146 have been added. New Claims 101-146 recite the elements of original Claim 23 in independent format. The Examiner has indicated that Claim 23 would be allowable if rewritten in independent format. Accordingly, the Applicants contend that new Claims 101-146 are patentable over the prior art.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PRTS-038US2.

Respectfully submitted,
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